

PRESS RELEASE

Gradientech Submits QuickMIC® to the U.S. FDA for 510(k) Clearance

Uppsala, Sweden, November 19, 2025. The diagnostics company Gradientech today announces the submission of a 510(k) premarket notification to the U.S. Food and Drug Administration (FDA) for its QuickMIC® diagnostic system for ultra-rapid antimicrobial susceptibility testing (AST) of bacterial isolates.

QuickMIC is currently the fastest phenotypic AST system on the market, delivering results within 2-4 hours directly from positive blood culture samples. This enables same-day optimisation of antibiotic therapy for sepsis patients — a critical improvement over traditional methods, which often take up to two days. The system is CE marked and implemented in routine clinical diagnostics across an expanding network of European hospitals.

To further expand and broaden the clinical utility and market reach of the QuickMIC system, the FDA studies have included both positive blood cultures and bacterial isolates as sample types, with this initial 510(k) submission covering the isolate workflow. Upon FDA clearance, Gradientech's U.S. commercial partner, Hardy Diagnostics, will begin the commercialisation of QuickMIC for diagnostic use in the American market.

"Ultra-rapid AST is redefining the future of clinical microbiology," says Sara Thorslund, CEO and co-founder of Gradientech. "QuickMIC delivers results within only a few hours, enabling faster, targeted antibiotic therapy. Including bacterial isolates in our FDA studies was a strategic decision — it provides hospital laboratories with flexibility and ensures that QuickMIC integrates seamlessly into existing microbiology workflows from day one."

QuickMIC® and its gram-negative panel are CE marked and commercially available in Europe. QuickMIC is classified as a Breakthrough Device by the U.S. Food and Drug Administration and available for Investigational Use Only in the U.S., but not 510(k) cleared.

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About Gradientech

Gradientech is a leader in ultra-rapid antibiotic susceptibility testing, developing next-generation diagnostics for infectious disease medicine. Our innovative diagnostic solutions aim to save lives, reduce healthcare costs, and combat the spread of antibiotic resistance - one of our greatest global health threats. Gradientech is headquartered in Uppsala, Sweden. Visit [gradientech.se](https://www.gradientech.se) for more information.